NOV 2 1 2000

K003109

510(k) SUMMARY
COMPLETE® brand Lubricating and Rewetting Drops

This summary uses the format provided in 21 CFR 807.92:

(a)(1) **Submitter:**

Paul J. Nowacki
Manager
Regulatory Affairs
Allergan
2525 Dupont Drive
Irvine CA 92612

Phone: (714) 246-6761
Fax: (714) 246-4272

Summary Prepared: September 19, 2000

(a)(2) **Device Trade Name:** COMPLETE® brand Lubricating and Rewetting Drops

Device Common Name: Soft (hydrophilic) Contact Lens Solution

Device Classification Names: Accessories to Contact Lens Solution (86LPN)

(a)(3) **Identification of Predicate Device:** COMPLETE® brand Lubricating and Rewetting Drops with the change in wording in the "Actions" section and no formulation changes are substantially equivalent to the product marketed with current claims and to other contact lens lubricating and rewetting solutions.

(a)(4) **Device Description:** COMPLETE® brand Lubricating and Rewetting Drops are a sterile, isotonic, buffered, preserved solution. This aqueous solution contains purified water, sodium chloride, preserved with polyhexamethylene biguanide 0.0001%, buffered with tromethamine, hydroxypropyl methylcellulose as a lubricant, tyloxapol as a surfactant, and edetate disodium as a chelating agent. This preparation contains no chlorhexidine, no thimerosal, and no other mercury containing ingredients.

(a)(5) **Intended Use (Indications for Use):**

COMPLETE® brand Lubricating and Rewetting Drops is indicated for use to lubricate and rewet soft (hydrophilic) contact lenses, disposable lenses and extended wear lenses before application and during wear.

(a)(6) **Comparison of Technological Characteristics:** The Actions section has been expanded. No changes have been made to the current product formulation.

(b)(1) **Nonclinical:** No new studies performed. Use nonclinical information from ***P910075/S7***

(b)(2) **Discussion of Clinical Data:** No studies performed. Use clinical data from ***P910075/S7***

(b)(3) **Conclusions Drawn from Data Supporting Equivalence Determination:** The purpose of this application is to provide a more descriptive "Actions" section on the package insert of COMPLETE® brand Lubricating and Rewetting Drops. There were no changes to the product formulation. Application P910075/S7 has already established the product's safety, efficacy and performance. No new studies are needed to show that the safety, efficacy and performance of COMPLETE® brand Lubricating and Rewetting Drops is substantially equivalent to other marketed lubricating and rewetting products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2000

Mr. Paul J. Nowacki
Manager, Regulatory Affairs
Allergan, Inc.
2525 Dupont Drive
Irvine, CA 92623-9534

Re: K003109
Trade Name: COMPLETE[R] brand Lubricating and Rewetting Drops
Regulatory Class: II
Product Code: 86LPN
Dated: October 3, 2000
Received: October 4, 2000

Dear Mr. Nowacki:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) NUMBER:
(IF KNOWN):

DEVICE NAME: COMPLETE® brand Lubricating and Rewetting Drops

INDICATIONS FOR USE:

COMPLETE® brand Lubricating and Rewetting Drops is indicated for use to lubricate and rewet soft (hydrophilic) contact lenses, disposable lenses and extended wear lenses before application and during wear.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Eric G, Ph.D.
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K003109

Prescription Use _____ OR Over-The-Counter-Use ✓
(Per 21 CFR 801.109 (Optional Format 1-2-96)